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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. |
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09/27/99 437 03/16/99 CHEN

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EXAMINER

CANELLA, K
ART UNIT PAPER NUMBER

1642
DATE MAILED:

02/13/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/270,437

Applicant(s)
Chen et al

Examiner
Karen Canella

Group Art Unit
1642



- ☐ Responsive to communication(s) filed on _____
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 30 days month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

- ☒ Claim(s) 1-109 _____ is/are pending in the application.
- Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☐ Claim(s) _____ is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☒ Claims 1-109 _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

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DETAILED ACTION

Election/Restriction

- I. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Claims 53-73, 80-84, 108 and 109, drawn to isolated nucleic acids of SEQ ID NO:5-8, expression vectors, hosts, compositions and kits thereof, classified in class 536, subclass 23.5, class 435, subclass 320.1 and class 424, subclass 93.21.
 - II. Claims 74-79 and 85, drawn to cancer associated antigen encoded by SEQ ID NO:5-8, and compositions thereof, classified in class 530, subclasses 324-328 and 350.
 - III. Claims 86 and 87, drawn to antibodies which bind to cancer associated antigen encoded by SEQ ID NO:5-8, classified in class 530, subclass 387.7.
 - IV. Claims 88-91, 106 and 96-98 in part, drawn to methods for screening for a possible pathological condition and methods for determining the regression, progression and onset of a cancerous condition comprising assaying for antibodies specific to cancer associated antigen encoded by SEQ ID NO:5-8, classified in class 435, subclass 7.1 and class 436, subclass 501. Claims 96-98 will be examined with this group to the extent that they read on a method comprising assaying for antibodies specific to said cancer associated antigen
 - V. Claims 92-95, and 102-104, drawn to methods for screening for a possible pathological condition and methods for determining the regression, progression and onset of a cancerous condition comprising assaying for nucleic acids, classified in class 435, subclass 6 and class 436, subclass 504.
 - VI. Claims 99-101, 105 and 96-98 in part, drawn to methods for screening for a possible pathological condition and methods for determining the regression, progression and onset of a cancerous condition comprising assaying for cancer

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associated antigen encoded by SEQ ID NO:5-8, classified in class 435, subclass 7.23 and class 436, subclass 501. Claims 96-98 will be examined with this group to the extent that they read on a method comprising assaying for said cancer associated antigen.

VII. Claims 107 and 96-98 in part, drawn to methods for screening for a possible pathological condition and methods for determining the regression, progression and onset of a cancerous condition comprising assaying for cytolytic T-cells and immunoreactive cells specific for a peptide derived from a cancer associated antigen encoded by SEQ ID NO:5-8, classified in class 435, subclass 7.24 and class 436, subclass 504. Claims 96-98 will be examined with this group to the extent that they read on a method comprising assaying for cytolytic T-cells specific for a peptide derived from said cancer associated antigen

2. The inventions are distinct, each from the other because of the following reasons:

Inventions of Groups I, II, and III are structurally and functionally different products which are made by different methods and have different uses. The examination of all groups would require different searches in the U.S. Patent Shoes and the scientific literature and would require the consideration of different patentability issues.

The methods of Groups IV, V, VI, and VII differ in the method objectives, method steps and parameters and in the reagents used.

Inventions I and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the nucleic acid of group I can be used in an in vitro mutagenesis assay.

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Inventions II and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the protein of Group II can be used to raise the antibody of Group III.

Inventions III and VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used to raise an antiidiotypic antibody.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter and because the searches required for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

3. Because of the complexity of the claims, telephonic restriction was not attempted.
4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).
5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

February 11, 2001


KAREN A. CANELLA
PATENT EXAMINER
TECHNOLOGY CENTER 1610